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23859 7590 05/27/2008

NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER

BRADLEY, CHRISTINA

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/27/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,360

09/25/2003

James C. Powers

07040.0027U1

7114

TITLE OF INVENTION: KETOAMIDE INHIBITORS IN CHRONIC NERVE DISEASE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	08/27/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23859 7590 05/27/2008

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,360 09/25/2003 James C. Powers 07040.0027U1 7114

TITLE OF INVENTION: KETOAMIDE INHIBITORS IN CHRONIC NERVE DISEASE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$720 \$300 \$0 \$1020 08/27/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
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BRADLEY, CHRISTINA 1654 514-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,360	09/25/2003	James C. Powers	07040.0027U1	7114
23859	7590	05/27/2008	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			BRADLEY, CHRISTINA	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 05/27/2008				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 385 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 385 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

10/671,360

Applicant(s)

POWERS ET AL.

Examiner

Art Unit

Christina Marchetti Bradley

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the request for continued examination filed 02/11/2008.
2. ☒ The allowed claim(s) is/are 34-39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 10/20/2003
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

/Cecilia Tsang/
Supervisory Patent Examiner
Art Unit 1654

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher L. Curfman on 5/8/2008.

The application has been amended as follows:

1-32. (Canceled)

Cancel claim 33.

34. A method for treating axonal degeneration of the peripheral nervous system of a patient comprising administering to the patient a ~~The method of claim 33, wherein the compound is~~ selected from the group consisting of:

Z-Leu-Nva-CO-NH-CH₂-2-pyridyl,

Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆F₅,

Z-Leu-Phe-CO-NH-(CH₂)₂Ph,

Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄-3-OC₆H₄(3-CF₃),

Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄(4-OCH₂Ph),

Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄(4-OPh),

Z-Leu-Phe-CO-NH-CH₂-2-quinolinyl,

Z-Leu-Abu-CO-NH-(CH₂)₂C₆H₄(3-OCH₃),

Z-Leu-Abu-CO-NH-(CH₂)₂C₆H₄(4-OCH₃),

Z-Leu-Abu-CO-NH-CH₂CH(OH)-1-C₁₀H₇,

Z-Leu-Phe-CO-NH-(CH₂)₃-4-morpholinyl,

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Z-Leu-Abu-CO-NH-(CH₂)₂C₆H₄(2-OCH₃),
Z-Leu-Abu-CO-NH-CH₂-2-quinolinyl,
Z-Leu-Abu-CO-NH-(CH₂)₂-2-(N-methylpyrrole),
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₄-3-OC₆H₄(3-CF₃),
Z-Leu-Abu-CO-NH-(CH₂)₂C₆H₅,
Z-Leu-Phe-CO-NH-Et,
Z-Leu-Abu-CO-NH-CH₂CH(OC₂H₅)₂,
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₄(4-OPh),
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₄(4-OCH₂Ph),
Z-Leu-Abu-CO-NH-CH₂C₆H₅,
Z-Leu-Phe-CO-NH-(CH₂)₂NH-biotinyl,
Z-Leu-Phe-CO-NH-(CH₂)₃-2-tetrahydroisoquinolinyl,
Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₃(3,4-(OCH₂Ph)₂),
Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄(4-OCH₃),
Z-Leu-Nva-CO-NH-(CH₂)₃-4-morpholinyl,
Z-Leu-Abu-CO-NH-CH₂-1-isoquinolinyl,
Z-Leu-Abu-CO-NH-Et,
Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄-3-OC₆H₃(3,4-Cl₂),
Z-Leu-Abu-CO-NH-Me,
Z-Leu-Abu-CO-NH-(CH₂)₃-1-imidazolyl,
Z-Leu-Abu-CO-NH-(CH₂)₂-3-indolyl,
Z-Leu-Abu-CO-NH-(CH₂)₃-2-tetrahydroisoquinolinyl,
Z-Leu-Abu-CO-NH-CH₂-2-tetrahydrofuryl,
Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄(4-N(CH₃)₂),
Z-Leu-Phe-CO-NH-*n*-Pr,
Z-Leu-Abu-CO-NH-CH₂CH(OH)-2-C₁₀H₇,
Z-Leu-Phe-CO-NH-Me,
Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄(3-CF₃),
Z-Leu-Abu-CO-NH-(CH₂)₃-1-tetrahydroquinolinyl,
Z-Leu-Abu-CO-NH-(CH₂)₂C₆H₄(4-OH),

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Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₂(3,4,5-(OCH₃)₃),
Z-Leu-Phe-CO-NH-(CH₂)₃-1-tetrahydroquinolinyl,
Z-Leu-Abu-CO-NH-(CH₂)₂-2-pyridyl,
Z-Leu-Abu-CO-NH-CH₂-C₆H₇(1,3,3-(CH₃)₃-5-OH),
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₄(3-CF₃),
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₃(3,4-(OCH₂Ph)₂),
Z-Leu-Abu-CO-NH-(CH₂)₅OH,
Z-Leu-Abu-CO-NH-CH₂CH(OCH₃)₂,
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₄-3-OC₆H₃(3,4-Cl₂),
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₄(3-OPh),
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆H₄(4-N(CH₃)₂),
Z-Leu-Abu-CO-NH-CH₂-2-pyridyl,
Z-Leu-Abu-CO-NH-(CH₂)₂O(CH₂)₂OH,
Z-Leu-Phe-CO-NH-CH₂-2-pyridyl,
Z-Leu-Abu-CO-NH-(CH₂)₂NH-biotinyl,
Z-Leu-Abu-CO-NH-CH₂-C₆H₁₁,
Z-Leu-Phe-CO-NH-CH₂CH(OH)C₆F₅,
Z-Leu-Abu-CO-NH-CH₂-2-furyl,
Z-Leu-Abu-CO-NH-(CH₂)₃C₆H₅,
Z-Leu-Abu-CO-NH-(CH₂)₂OH,
Z-Leu-Abu-CO-NH-CH₂CH(OH)C₆H₄(3-OPh),
Z-Leu-Abu-CO-NH-(CH₂)₂-4-morpholinyl,
Z-Leu-Abu-CO-NH-CH₂CH(OH)Ph,
Z-Leu-Abu-CO-NH-CH₂-4-pyridyl,
Z-Leu-Abu-CO-NH-(CH₂)₃-1-pyrrolidine-2-one,
Z-Leu-Phe-CO-NH-CH₂CH(OH)Ph,
Z-Leu-Abu-CO-NH-CH₂C₆H₃(3,5-(OCH₃)₂),
Z-Leu-Nva-CO-NH-CH₂CH(OH)Ph,
Z-Leu-Abu-CO-NH-CH₂-8-caffeinylyl,
Z-Leu-Abu-CO-NH-*n*-Pr,

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Z-Leu-Abu-CO-NH-CH₂-3-pyridyl, ~~and~~
Z-Leu-Phe-CO-NH-CH₂Ph, and
Z-Leu-Abu-CONH-(CH₂)₃-4-morpholinyl;
wherein Z is a benzyloxycarbonyl group.

33. The method of claim 3~~3~~4, wherein the compound is Z-Leu-Abu-CONH-(CH₂)₃-4-morpholinyl.
34. The method of claim 3~~3~~4, wherein the axonal degeneration of the peripheral nervous system is chemically-induced axonal degeneration.
35. The method of claim 3~~3~~4, wherein the compound is administered concurrently with an anti-hyperproliferative agent.
36. The method of claim 3~~3~~4, wherein the compound is administered subsequent to administration of an anti-hyperproliferative agent.
37. The method of claim 3~~3~~4, wherein the compound is administered orally.

The definition for the variable Z in claim 32 is found in the specification as originally filed on page 5, lines 32-33.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571)272-9044. The examiner can normally be reached on Monday-Friday, 9:00 A.M. to 3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654